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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/557,611	11/22/2005	Atsutoshi Ikesue	28729U	1480

20529 7590 01/15/2009

THE NATH LAW GROUP
112 South West Street
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EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
01/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/557,611	IKESUE ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 4, 12, 13* is/are pending in the application.

4a) Of the above claim(s) *12 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed October 14, 2008, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1 – 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertrand et al. (FR 2804024) in view of Swingle et al. (1985). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed July 16, 2008 and those set forth below. This rejection is no longer applied to cancelled claims 5 – 11.

Applicant traverses this rejection on the grounds that a prima facie case of obviousness has not been established. Neither Bertrand et al or Swingle et al. teach or suggest all the claim limitations. Bertrand et al. discloses a composition comprosing ketoprofen and optionally an antioxidant such as BHT or BHA whereas Swingle et al. discloses the anti-inflammatory effect of antioxidants such as BHA, BHT and propyl gallate. Swingle et al. does not teach or suggest a composition containing both BHT or propyl gallate. Additionally, no teaching or suggestion to motivate one or ordinary skill to combine these references has been provided in that the reliance on *In re Kerkhoven* showing that the combination of compositions taught as useful for the same purpose is not sufficient as a reason that would have prompted a person of ordinary skill in the relevant field in the way the claimed new invention does. Even if the combination of

elements are found in the combination of references, there is no teaching or suggesting in the references that the combination of ingredients as claimed would exert a synergistic effect in inhibiting/reducing photosensitivity/phototoxicity of a transdermal formulation containing ketoprofen as an active ingredient. This synergistic effect is not predictable and is significantly greater than that inhibition/reduction that would have been predicted or expected as the results are more than merely additive. Inventive example 4 – 5 and comparative examples 1 – 4 demonstrate the synergistic effects of compositions comprising 2% ketoprofen, 1.0% BHT and 0.2% propyl gallate (PG) or 2% ketoprofen, 0.5% BHA and 0.2% PG in comparison to composition comprising 2% ketoprofen and the other components individually in inhibiting auricular edema.

These arguments are not found to be fully persuasive. *In re Kerkhoven* does provide a reason for one of ordinary skill to combine the two references - that the compositions of both Bertrand et al. and Swingle are anti-inflammatory compositions and because they are taught as useful for the same purpose, compositions for the treatment of inflammation, one of ordinary skill in the art would be motivated to prepare a composition comprising ketoprofen, propyl gallate and a phenolic radical scavenger such as BHA or BHT.

The compositions comprising 2% ketoprofen, 1.0% BHT and 0.2% PG or 2% ketoprofen, 0.5% BHA and 0.2% PG do show more than additive effects in inhibiting auricular edema. However, these two examples are not sufficient to show a synergistic effect for all non-steroidal anti-inflammatory analgesics, all alkyl esters of gallic acid and all phenolic radical scavengers having a branched-chain lower alkyl group in any

amount as recited in the instant claims. The data presented in tables 1 – 3 regarding hemolysis inhibition, again for compositions comprising ketoprofen, and combinations of PG with BHA, BHT or BHT appear to show that some combinations of PG and phenolic radical scavengers at some concentrations are not synergistic. For example, the hemolysis inhibition of a composition comprising ketoprofen, 1 µg/mL PG and 1 µg/mL thymol appears to have a less than additive effect on hemolysis inhibition in comparison to the inhibition provided by compositions comprising ketoprofen and 1 µg/mL PG or ketoprofen and 1 µg/mL thymol (see table 3). Therefore, the evidence of synergism between the components of the claimed composition is not commensurate in scope with the compositions recited in the instant claims and this rejection is MAINTAINED.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. This application contains claims 12 and 13 drawn to an invention nonelected with traverse in the reply filed on February 7, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW